DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA Public Health Notification: Risk of Electromagnetic Interference with Medical Telemetry Systems Operating in the 460-470 MHz Frequency Bands

Issued: November 16, 2005

This is to notify you that after December 31, 2005, any medical telemetry systems operating in the 460-470 MHz frequency bands will be at increased risk for interference, which could compromise patient safety. In January 2006 the Federal Communications Commission (FCC) will begin issuing new licenses for mobile radio transmitters to operate in the 460-470 MHz band.

Background

In 2000, the FCC dedicated a portion of the radio spectrum for wireless medical telemetry. This part of the spectrum is known as the Wireless Medical Telemetry Service (WMTS). The WMTS bands include 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz. With Spectrum dedicated for medical telemetry use, the FCC's intent for the past several years has been to grant new licenses to higher power mobile radio users in the 460-470 MHz band. However, because of the potential for serious interference with existing medical telemetry systems the FCC has delayed implementing this change in order to allow time for medical facilities to migrate out of the 460-470 MHz band. **This freeze on new land mobile licenses in the 460-470 MHz band will expire on December 31, 2005.**

After December 31, 2005, the FCC will begin granting a great many licenses for mobile radio transmitters that will use new channels in the 460-470 MHz band. The new licenses will be for transmitters of 2 Watts or higher. It is estimated that there are several hundred thousand users waiting for these new channels. Most of the radio users in this band will include hand-held and other mobile transmitters such as those operated by police; fire and rescue; taxis; and commercial trucks. These users could likely operate in and around your hospital.

Wireless medical telemetry equipment still using channels in the 460 – 470 MHz band after December 31, 2005, could be adversely affected by mobile radios operating under the new FCC licenses. According to tests conducted by the FDA, the transmitters operating under new licenses in this frequency band can interfere with medical telemetry systems. This could lead to lapses in patient monitoring and missed alarm events, putting patients at risk. The anticipated interference will not be limited to urban areas. Any medical facility in the vicinity of a mobile radio could be affected.

Recommendations

We recommend that you:

- Determine if your current wireless medical telemetry systems are operating in the 460-470 MHz frequency band. You may need to consult with the telemetry equipment manufacturer to determine this.

- Migrate out of the 460-470 MHz band if you are operating wireless medical telemetry equipment in that band and move to less vulnerable frequencies, such as the WMTS bands, by December 31, 2005.

- Register any WMTS equipment with the frequency coordinator for WMTS – the American Society for Healthcare Engineering (ASHE) of the American Hospital Association (AHA). Registration of WMTS equipment is required by the FCC.

- Assess and manage the risks for **all** medical telemetry. Medical telemetry still operating in the TV channels 7-13 (174-216 MHz), 14-36 (470 -608 MHz), and 38-46 (614-668 MHz) are particularly at risk. This is because in July 2005, the FCC ordered most major commercial broadcasters in the top 100 markets to operate their Digital TV (DTV) transmitters at their maximum licensed power. All others broadcasters will be required to do so by July 2006.

- Establish lines of communication or meet regularly with local broadcasters so that you can be aware of local changes in the high-power broadcast use of the RF spectrum.

Getting More Information

Additional information on wireless medical telemetry, WMTS, and frequency coordination can be found on the ASHE web site at http://www.ashe.org/ashe/wmts/registration.html.

Additional information from FCC regarding lifting the freeze on high powered licenses in the 460-470 MHz frequency band can be found at http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-04-2071A1.pdf and http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-249481A1.pdf. General information from FCC on WMTS can be found at http://wireless.fcc.gov/services/personal/medtelemetry/.

Additional and background information from FDA on WMTS can be found on our web site at http://www.fda.gov/cdrh/safety/emimts.html.

If you have questions regarding this Notification that are related to FDA issues, please contact Nancy Pressly, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

All of the FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: http://list.nih.gov/archives/dev-alert.html.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to interference with medical telemetry, you should follow the reporting procedure established by your facility.

If a telemetry system fails to function due to interference or any other reason, it is a device malfunction. We encourage you to report these malfunctions directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm.

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration